

## CLAIMS

1. A heart valve prosthesis having a plurality of leaflets encircling a flow opening and of size to coapt to form a valve, each leaflet  
5 having a free outflow edge at the outflow end of the leaflet, wherein the free outflow edge forms a convex (relative to the leaflet) curve in the plane of the leaflet.

2. A method for forming a heart valve prosthesis comprising  
10 the step of forming a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a valve, wherein each leaflet has a free outflow edge at the outflow end of the leaflet, wherein the free outflow edge forms a convex (relative to the leaflet) curve in the plane of the leaflet.

15

3. A method for forming a heart valve prosthesis comprising the steps of:

assembling the valve, by steps comprising forming a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a  
20 valve, and forming an outer sheet joined to the leaflets around an inflow end and along commissures formed where adjacent leaflets join,

after assembly of at least the leaflets and outer sheet of the valve, shaping the leaflets and/or outer sheet to a desired shape,

fixing the leaflets and/or outer sheet of the valve in the desired  
25 shape.

4. The method of claim 3 wherein the leaflets and outer sheet are shaped to a desired shape and fixed in the desired shape, and wherein the shaping of the outer sheet is of a portion of the outer sheet on the

outflow side of the join between the outer sheet and the leaflets around the inflow end.

5        5.     A method for forming a stentless heart valve prosthesis comprising the steps of:

             forming a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a valve,

             forming an outer sheet joined to the leaflets around an inflow end and along commissures formed where adjacent leaflets join,

10        wherein the join between the outer sheet and the leaflets around the inflow end is at the periphery of the leaflets, and the outer sheet extends by a distance between 0.3 and 4mm beyond the join with the leaflets at the inflow end, on the inflow side of the join, or the join between the outer sheet and the leaflets around the inflow end is at the periphery of the outer  
15        sheet, and the leaflets extend by a distance between 0.3 and 4mm beyond the join with the outer sheet at the inflow end, on the inflow side of the join.

             6.     The method of claim 5, further comprising the step of after  
20        assembly of at least the leaflets and outer sheet of the valve, shaping the leaflets and/or outer sheet to a desired shape and fixing the leaflets and/or outer sheet of the valve in the desired shape.

             7.     The method of any one of claims 3 to 6 wherein each leaflet  
25        has a free outflow edge at the outflow end of the leaflet, wherein the free outflow edge forms a convex (relative to the leaflet) curve in the plane of the leaflet.

8. The method of any one of claims 3, 4, 6 or 7 wherein the leaflets and/or outer sheet are shaped to a desired shape by inserting a shaping device into a pocket formed by a leaflet and the outer sheet.

5 9. The method of claim 8 wherein the shaping device is a ball formed of a resilient material, preferably cotton wool.

10 10. The method of any one of claims 3, 4, 6 to 9 wherein the leaflets and outer sheet are assembled from pericardium which has not been fixed, and fixing the leaflets and/or outer sheet of the valve in the desired shape is performed by treatment with glutaraldehyde.

15 11. The method of any one of claims 3, 4, 6 to 10 wherein after assembly and fixing of the valve the outer sheet is trimmed close to the join between the outer sheet and the leaflets on the outflow side of the join.

12. A valve obtainable by the method of any one of claims 2, 4 to 11.

20

25 13. A stentless heart valve prosthesis comprising a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a valve, an outer sheet joined to the leaflets around an inflow end and along commissures formed where adjacent leaflets join, wherein the join between the outer sheet and the leaflets around the inflow end is at the periphery of the leaflets, and the outer sheet extends by a distance between 0.3 and 4mm beyond the join with the leaflets at the inflow end, on the inflow side of the join, or the join between the outer sheet and the leaflets around the inflow end is at the periphery of the outer sheet, and the

leaflets extend by a distance between 0.3 and 4mm beyond the join with the outer sheet at the inflow end, on the inflow side of the join

14. The valve of claim 13 wherein the outer sheet of the valve  
5 has a shape resembling the shape of natural aortic sinuses.

15. The valve of claims 13 or 14 wherein the outer sheet is  
trimmed close to the join between the outer sheet and the leaflets on the  
outflow side of the join.

10

16. The valve of claim 13, 14 or 15 wherein each leaflet has a  
free outflow edge at the outflow end of the leaflet, wherein the free  
outflow edge forms a convex (relative to the leaflet) curve in the plane of  
the leaflet.

15

17. The valve or method of any of the preceding claims wherein  
the valve has three leaflets.

18. The valve or method of any of the preceding claims wherein  
20 the valve is stentless.

19. The valve or method of claim 1 or 2 wherein the valve  
comprises an outer sheet joined to the leaflets around an inflow end and  
along commissures formed where adjacent leaflets join.

25

20. The valve or method of any one of the preceding claims  
wherein the leaflets and/or outer sheet (where present) are formed from  
material other than natural valve material.

21. The valve or method of claim 20 wherein the leaflets are formed from a sheet material.

22. The valve or method of claim 20 or 21 wherein the leaflets  
5 and/or outer sheet are formed from a biological material.

23. The valve or method of any one of the preceding claims wherein the leaflets and/or outer sheet are formed from pericardium.

10 24. The valve or method of any one of the preceding claims wherein the leaflets are formed by a single piece of sheet material.

25. A valve prosthesis according to any one of the preceding claims for use in medicine.

15

26. Use of a valve prosthesis according to any one of the preceding claims in the manufacture of a medicament for the treatment of a patient in need of repair or replacement of a heart valve.

20 27. A method of repairing a heart valve comprising the step of providing a valve prosthesis as defined in any one of the preceding claims, and suturing the valve prosthesis to the heart or blood vessel tissue of the patient.

25 28. A method of repairing a heart valve comprising the steps of:  
(1) providing a valve prosthesis as defined in any one of the preceding claims, wherein the valve has an outer sheet;  
(2) if not already done, trimming the outer sheet close to the join between the outer sheet and the leaflets on the outflow side of the join;

(3) suturing the valve prosthesis to the heart or blood vessel tissue of the patient with a single suture row.

29. A stentless heart valve prosthesis suitable for replacement of  
5 the aortic root comprising an outer wall and a plurality of leaflets positioned inside the outer wall, encircling a flow opening and of size to coapt to form a valve, wherein the outer wall and leaflets are formed from material other than natural valve material.

10 30. A method for forming a stentless heart valve prosthesis suitable for replacement of the aortic root as defined in claim 29 comprising the steps of forming an outer wall and a plurality of leaflets positioned inside the outer wall, encircling a flow opening and of size to coapt to form a valve, wherein the outer wall and leaflets are formed from  
15 material other than natural valve material.

31. A stentless heart valve prosthesis suitable for replacement of the aortic root comprising a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a valve, an outer wall joined to the  
20 leaflets around an inflow end and along commissures formed where adjacent leaflets join, wherein the outer wall and leaflets are formed from material other than natural valve material, wherein the join between the outer wall and the leaflets around the inflow end is at the periphery of the leaflets, and the outer wall extends by a distance between 0.3 and 4mm  
25 beyond the join with the leaflets at the inflow end, on the inflow side of the join, or the join between the outer sheet and the leaflets around the inflow end is at the periphery of the outer sheet, and the leaflets extend by a distance between 0.3 and 4mm beyond the join with the outer wall at the inflow end, on the inflow side of the join.

32. The valve prosthesis of claim 29 or 31 or method of claim 30 wherein the outer wall is formed from a biological material (other than natural valve material) and a non-biological, biocompatible material.

5

33. The valve prosthesis or method of claim 32 wherein the outer wall is formed from pericardium and a woven fabric, preferably polyester (PET).

10

34. The valve prosthesis or method of any one of claims 29 to 33 wherein the leaflets are formed from a biological material, for example pericardium.

15

35. The valve prosthesis or method of any one of claims 29 to 34 wherein each leaflet has a free outflow edge at the outflow end of the leaflet, wherein the free outflow edge forms a convex (relative to the leaflet) curve in the plane of the leaflet.

20

36. The method of any one of claims 30 to 35 comprising the steps of:

assembling the valve, by steps comprising forming a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a valve, and forming an outer wall joined to the leaflets around an inflow end and along commissures formed where adjacent leaflets join;

25

after assembly of at least the leaflets and outer wall of the valve, shaping the leaflets and/or outer wall to a desired shape,

fixing the leaflets and/or outer wall of the valve in the desired shape.

37. The method of any one of claims 30 to 35 comprising the steps of:

forming a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a valve;

5 forming an outer wall joined to the leaflets around an inflow end and along commissures formed where adjacent leaflets join;

wherein the join between the outer wall and the leaflets around the inflow end is at the periphery of the leaflets, and the outer wall extends by a distance between 0.3 and 4mm beyond the join with the leaflets at the inflow end, on the inflow side of the join; or the join between the outer wall and the leaflets around the inflow end is at the periphery of the outer wall, and the leaflet extends by a distance between 0.3 and 4mm beyond the join with the outer wall at the inflow end, on the inflow side of the join.

15

38. The method of claim 37 further comprising the steps of after assembly of at least the leaflets and outer wall of the valve, shaping the leaflets and/or outer wall to a desired shape and fixing the leaflets and/or outer wall of the valve in the desired shape.

20

39. The method of claim 36 or 38 wherein the leaflets and/or outer sheet are shaped by inserting a shaping device into a pocket formed by a leaflet and the outer wall.

25

40. The method of claim 39 wherein the shaping device is a ball formed of a resilient material, for example cotton wool.

41. The method of any one of claims 36, 38 to 40 wherein the outer wall is shaped to a desired shape and fixed in the desired shape.



42. The method of any one of claims 36, 38 to 41 wherein the leaflets and outer sheet are assembled from pericardium which has not been fully fixed, and fixing the leaflets and/or outer sheet of the valve in  
5 the desired shape is performed by treatment with glutaraldehyde.

43. The method or valve prosthesis of any one of claims 29 to 42 wherein the outer wall or sheet has a height ( $h_o$ ) that is between 1 and 15 cm, preferably between 4 and 12 cm, still more preferably between  
10 about 8 and 10 cm greater than the maximum height ( $h$ ) of the leaflets.

44. A stentless heart valve prosthesis suitable for replacement of the aortic root obtained or obtainable by a method according to any one of claims 30, 32 to 42.  
15

45. The valve of any one of claims 29, 31 to 35, 43 or 44 wherein the outer sheet of the valve has a shape resembling the shape of natural aortic sinuses.

20 46. The valve prosthesis or method of any one of claims 29 to 45 wherein the valve has three leaflets.

47. The valve prosthesis or method of any one of claims 29 to 46 wherein the leaflets are formed by a single piece of sheet material.  
25

48. A valve prosthesis according to any one of claims 29 to 47 for use in medicine.

49. The use of a valve prosthesis according to any one of claims 29 to 48 in the manufacture of a medicament for the treatment of a patient in need of repair or replacement of a heart valve and in need of replacement of a portion of the aortic wall.

5

50. A method for repairing a heart valve comprising the step of providing a valve prosthesis according to any one of claims 29 to 49, and suturing the valve prosthesis to the heart or blood vessel tissue of the patient.

10

51. The method of claim 50 comprising the step of trimming the outer wall to the desired length, depending on the extent of aortic tissue to be replaced.